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Via Electronic Submission

Professor Wendy Wagner
University of Texas Law School
Member, Administrative Conference of the United States
Committee on Regulation
http://www.acus.gov/forum/

Re: Comments on Science in the Administrative Process, 76 Fed. Reg. 64,298 (Oct. 18, 2011)

Dear Professor Wagner:

On behalf of the Styrene Information and Research Center, Inc. (SIRC),[1] we are pleased to provide comments on your research concerning "Science in the Administrative Process," conducted under the auspices of the Administrative Conference of the United States (ACUS). As stated in the draft outline, the study focuses on "strengthening internal agency processes for communicating how it uses science for regulation."[2]

I. What is Science?

The current administration has consistently highlighted the relationship between science and governance. President Obama called for the restoration of science in his inaugural address,[3] the Office of Science and Technology Policy disseminated administrative guidelines for ensuring

[1] The Styrene Information and Research Center, Inc. (SIRC) was formed in 1987 as the principal focal point for public information and research on styrene. It is a non-profit organization consisting of voting member companies involved in the manufacturing or processing of styrene, and associate member companies that fabricate styrene-based products. Collectively, SIRC's membership represents approximately 95% of the North American styrene industry. SIRC serves as a liaison between industry, federal and state governments, and international agencies on health-related issues involving styrene. For more information visit: www.styrene.org.

[2] "Science in the Administrative Process: Take 2 (Draft Outline)," Wendy Wagner, University of Texas School of Law (Oct. 30, 2011), *available at* http://www.acus.gov/wp-content/uploads/downloads/2011/10/COR-Science-Project-Wagner-outline-10-31-11.pdf.

[3] *See* January 20, 2009 Inaugural Address, *available at* http://www.whitehouse.gov/blog/inaugural-address/.

"scientific integrity,"[4] and Administrator Jackson of the United States Environmental Protection Agency (EPA) commenced her tenure by directing employees not to disguise policy decisions as scientific findings.[5] Strengthening internal communication processes is a critical first step in enabling agencies to effectively use science.

There is a substantial body of literature on science and governance. Much of that literature focuses on the inevitable challenges to democratic principles presented by a seemingly endless stream of government decisions based on complex science, of which the majority of citizens either lack the ability or interest to gain an understanding.[6] Those issues are largely outside the scope of this inquiry, but underscore the need for agencies to communicate science in a straight-forward manner so that the average person can understand the basis for concern and, thus, should not be ignored in developing a framework for internal agency communications.

Before addressing science in the administrative process, the current study would be well-served by discussing or defining what is meant by science within the context of the paper. Even the term scientific method has a number of meanings. In general, we may say that the scientific method involves careful, systematic and open reasoning about empirical evidence.

Another meaning of scientific method refers to the process of observation, development of a hypothesis and predictions based on that hypothesis, followed by experimentation, the results of which are used to validate or refine the hypothesis and, ultimately, to develop a theory that consistently and accurately predicts the phenomena being observed. In this sense, a theory is a logical and consistent model or framework that describes some aspect of our observable universe. While the scientific method is widely taught, there is a body of literature that criticizes this formulation as an inadequate or misleading description of the basis for scientific progress or discovery.[7] We agree that this strict definition does not sufficiently embrace scientific *thinking*.

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[4] *See* "Memorandum for the Heads of the Executive Departments and Agencies on Scientific Integrity," from John P. Holdren, Director of the Office of Science and Technology (Dec. 17, 2010), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.

[5] *See* "Opening Memorandum to EPA Employees," from EPA Administrator Lisa P. Jackson (Jan. 23, 2009), *available at* http://blog.epa.gov/administrator/2009/01/26/opening-memo-to-epa-employees/.

[6] *See, e.g.*, Sheila Jasanoff, "Technologies Of Humility: Citizen Participation In Governing Science," Minerva 41:223-244 (2003). Sheila Jasanoff is Pforzheimer Professor of Science and Technology Studies at Harvard University's John F. Kennedy School of Government. Her publications include *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press, 1990). A Science and Democracy Network bibliography is available at: http://www.hks.harvard.edu/sdn/bibliography/.

[7] Some examples include: Thomas S. Kuhn, "The Structure of Scientific Revolutions," N.R. Hanson, "Patterns of Discovery," and Paul Feyerabend, "Against Method." Suspicion followed by discovery is "the core of the empirical program of quantitative natural science." Fred L. Bookstein, "Geometry as Cognition in the Natural Sciences." The easiest, quick read on this are postings by Dr. Terry Halwes, who appears to be a professor in the Department of

(continued …)

Steven Schafersman makes a helpful distinction between the scientific method and scientific reasoning.

> *The scientific method is practiced within a context of scientific thinking, and scientific (and critical) thinking is based on three things: using empirical evidence (empiricism), practicing logical reasoning (rationalism), and possessing a skeptical attitude (skepticism) about presumed knowledge that leads to self-questioning, holding tentative conclusions, and being undogmatic (willingness to change one's beliefs). These three ideas or principles are universal throughout science; without them, there would be no scientific or critical thinking.*[8]

Valid implementation of the scientific method has practical implications for a wide array of agencies.[9]

II. Common and Unshared Aspects of Science and the Administrative Process

While the predominant view treats science and the administrative process as two very different types of endeavors, a premise of these comments is that there are many similarities meriting emphasis. After all, the essence of both disciplines is process: the process of discovery governed by the scientific method in science; and the process of rulemaking governed by the Administrative Procedure Act in federal agencies. Using the examples below, we compare scientific and administrative processes. This is one starting point for clarifying the intent of administrative practices among agency scientists. It may also refine the agency's managers on the role and limits of science in the administrative process.[10] Discussions of such comparisons can themselves lead to improved understanding and communication.

For example, well-designed test protocols are a cornerstone of experimental science. To produce comparable and reliable data, however, good laboratory practices are needed to implement test protocols properly. By analogy, administrative procedures are akin to test protocols. Without the right procedures, the probability of obtaining valid and meaningful results is very low. But, even with the right procedures, administrative proceedings need the equivalent of good

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Psychiatry at Yale University School of Medicine, available at: http://www.dharma-haven.org/science/myth-of-scientific-method.htm.

[8] Steven D. Schafersman, "An Introduction to Science: Scientific Thinking and the Scientific Method" (Jan. 1994), *available at* http://www.freeinquiry.com/intro-to-sci.html.

[9] *See, e.g.,* "Report on the Relationship of the Scientific Method to Scientifically Valid Research and Education Research," prepared for the U.S. Department of Education Institute of Education Sciences by Norman W. Edmund, Edmund Scientific Co. (Dec. 2005).

[10] *See Reference Manual on Scientific Evidence*, Federal Judicial Center and National Research Council, pp. 51-52 (3d ed. 2011) (discussing how science and the law imprint on the same language different meanings, but despite these differences both disciplines share many of the same methods).

laboratory practices in terms of implementation. An agency may provide a comment period, but if the comments are not considered in a meaningful way, the intent of the procedural step is not realized. For scientists, applying the empiricism, rationalism and skepticism found in scientific thinking to the task at hand would be essential to establish a solid foundation for any administrative endeavor.

A. A Common Aspect: Replication and Transparency

In experimental science, the study report or manuscript must contain enough detail that other researchers can replicate the test protocol and compare their results with the original research. That replication or lack of replication will validate, modify, or invalidate the insights learned from the initial study.[11]

This ability to replicate is very much like the concept of transparency that is stressed in administrative proceedings. Transparency is used prominently in President Obama's guidance, in Lisa Jackson's 2009 memo on transparency in EPA operations, in the Information Quality Act, and in the National Research Council's review of EPA's Draft IRIS Assessment of Formaldehyde.[12]

Particularly in a democracy, the public needs to be able to walk, step-by-step, through the agency's decision-making process; we need to be able to follow the agency's line of reasoning and recreate the objective data on which it was based. This process, in many respects, is as important as the decision itself.

Besides serving the fundamental values of participatory democracy, this approach also serves the agency's institutional needs. Such a record is helpful for EPA when staff members review or revisit prior assessments. It also serves as a reference point or point of departure when the agency, guided by new data or direction, decides to change its approach.

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[11] The inability to replicate the results of scientific experiments has a broad array of consequences and its own implications for the use of science in the administrative process. The implications for commercial enterprises was the subject of a front page story in December 2, 2011, edition of the Wall Street Journal. The article was entitled "Scientists' Elusive Goal: Reproducing Study Results" (roughly 20% of academic studies being fully replicated, 64% not being replicated and the balance being partially replicated), available at http://online.wsj.com/article/SB10001424052970203764804577059841672541590.html?KEYWORDS=reproducing+study+results (subscription required).

[12] *See especially*, chapter 7, "Roadmap for Revision." The entire report is available as a free download at: http://www.nap.edu/catalog.php?record_id=13142.

B. Uncommon Aspects

While fact-based, logical and open-minded analysis are common process aspects of both science and the administrative process, agency communications would also benefit by understanding and respecting the differences between science and the administrative process. Indeed, many of the criticisms related to science and the administrative process have stemmed from the errors of ignoring scientific information or using science as a stealth mask for statutory or policy-based risk management decisions.

Agency reviews and analyses of the available scientific information would benefit by carefully honoring the scientific method within a framework and culture that nurtures scientific discourse. The role of the staff scientist can be unduly influenced in two ways. First, there can be agency demands for scientific conclusions when the level of uncertainty does not permit conclusions. Second, the operating culture within an agency can be influenced through the bias of viewpoints or considerations not appropriate to an open and objective review of the current state of the science. Embracing and elucidating the distinction between science and regulatory policy is critical to ensuring scientific integrity and enhancing policy debates in risk management decision-making.

For example, care should be taken to distinguish between data, the interpretation of data, the application of policy and the application of statutory or regulatory criteria to risk management decisions. Science is amoral. It is a wonderful vehicle for determining the degree of certainty related to a particular event, be it the time of the sun rise or the probability of developing cancer from certain behaviors. But, science does not inherently carry ethical, social or moral values for the events or processes it helps us to understand.[13] It is society's choice whether it builds power plants or makes bombs, or what levels of resources are applied to those endeavors. Science may inform our choices, and risk assessment is a valuable tool to sharpen our logic and understanding of potential outcomes, but the governmental risk management decision is necessarily made and applied within a statutory or legal framework.

[13] We stress that the amoral nature of the scientific process relates to the absence of a scientific ethic directing how new learning or abilities should be used. In contrast, the scientific process itself relies on the truthfulness of scientists in presenting protocols and results as well as transparency. External transparency may be intentionally avoided, for example, in matters of national security, and, in the private sector, to protect potential commercialization. National security or other considerations may be valid reasons for avoiding external transparency, but internal agency transparency should be observed to the greatest extent possible to facilitate internal agency communications. Personal privacy rights are an additional consideration, for example, with regard to the subjects of health studies.

The Bipartisan Policy Center explains it thus:

> *[D]ecisions about how much risk society should tolerate or what actions should be taken in the face of scientific uncertainty are not science questions, rather they concern policies and values. Matters such as risk and uncertainty need to be informed by scientific results, but science cannot tell policy makers how to act. True, distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both*.[14]

III. Communicating Clearly

This section presents suggestions to guide internal agency communications. While it focuses on internal practices, the application of good internal communication practices should improve the agency's ability to communicate to the public, in an intelligible manner, the bases for its decision.

A. "Science" versus "Regulatory Science"

The term "regulatory science" refers to agency scientific reviews conducted for the purpose of applying statutory or regulatory criteria to determine whether regulatory action is necessary and, if so, whether the proposed action is the appropriate one.[15] It is well recognized that regulatory science, produced to support governmental efforts to guard against risk, is fundamentally different from research driven by scientists' collective curiosity.[16] The development and use of regulatory science typically involves three distinct processes:

1. the development and collection of scientific data;
2. the interpretation and evaluation of scientific data; and

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[14] Bipartisan Policy Center, "Improving the Use of Science in Regulatory Policy" p. 15 (Aug. 5, 2009), *available at* http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf.

[15] *See, e.g.*, 42 U.S.C. § 241(b)(4), requiring that the Secretary of the Department of Health and Human Services publish a biennial report which contains a list of all substances (1) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens; and (2) to which a significant number of persons residing in the United States are exposed.

[16] Sheila Jasanoff, "Technologies of Humility: Citizen Participation in Governing Science." Minerva 41: 223-244, 229 (2003).

3. the application of criteria or "regulatory policy" to the scientific findings for purposes of making a risk management decision.

While an agency may, and indeed should, apply the scientific method in the first two stages, regulatory science departs from the traditional scientific discipline at stage three, where statutory or regulatory criteria and other value-based inputs come to bear.

For substances with either limited or extensive scientific literature, evaluating their potential toxicological effects presents challenges in the context of data interpretation and evaluation. Limited databases frequently call for extrapolation, while extensive databases regularly require the reconciliation of divergent results. In this regard, it is important to recognize and explain the relationships between data, interpretation of data, and the application of scientific principles and regulatory policy. The agency must determine, as a matter of policy, how to reconcile scientific uncertainty, weigh risk, and decide what approach is appropriate, taking into account the nature of the public health risk, the benefits that the chemical provides to society and the applicable legal criteria.

Agencies can strengthen accountability by developing internal guidelines and protocols that help clarify for both officials and the general public which aspects of a risk management decision are truly about scientific data and which concern policy. Indeed, the credibility of regulatory science ultimately rests upon factors that have more to do with transparency and accountability, than with the quality of science as assessed by review panels.[17] Such protocols should address how the agency plans to approach the three distinct stages involved in regulatory science reviews (*i.e.*, data collection, data interpretation and evaluation, and application of regulatory policy to scientific findings) in a logical and transparent manner, and should include the following accepted principles for communicating science in the administrative process:

- Agency communications relating to a proposed action should describe the primary scientific questions and the primary policy questions that need to be answered.[18] This should be combined with an explanation of the scientific procedure employed, and what policies were applied in the staff report. Importantly, individual determinations or recommendations that support the ultimate decision need to be separately stated and explained to provide a complete understanding of the policy or risk management decision the recommendations embody.
- If the available scientific literature leaves a significant level of uncertainty as to the degree to which effects can be predicted, this should be explicitly recognized and not hidden by seemingly precise impressions of numeric projections. For example, the available data might limit an agency's ability to prepare a quantitative risk assessment.

[17] *See id.* at 233.

[18] *Supra* note 14.

Such uncertainty may prompt the agency scientists to apply multiple safety factors under various science policies, resulting in a policy determination that a very low numeric value will be designated as a safe level. The scientific staff needs to scrupulously describe how it interpreted the scientific data and the default assumptions it employed. But agency scientists need to be equally clear in explaining the limits of knowledge and uncertainty, what science policies were applied, and the risk management implications. The agency risk manager needs to understand the range of projections so that final rules avoid the unintended extremes.

- Agencies must avoid disguising policy decisions as scientific findings,[19] and framing regulatory issues as debates solely about science.[20] Instead, in any draft or final document concerning science, agencies should clarify that they are not presenting scientific fact, but rather a policy judgment informed by their scientific literature review and their interpretation of the applicable statutory or regulatory criteria.[21]

B. Agencies and Their Review Panels Must Define the Scope of the Literature Review and Describe the Uncertainties and Limitations of Such Data

In any regulatory science review, the agency scientists should describe the criteria they use to determine which scientific papers to review and how those papers will be evaluated, and the proposed criteria should be open for public comment as early in the process as possible.[22] The clarification of these criteria will serve to gain early stakeholder consensus and reduce the likelihood of potential challenges to the quality, reliability and agency interpretation of scientific data late in the scientific review process. The benefits of "early" peer review are recognized by the Office of Management and Budget's (OMB) *Final Information Quality Bulletin for Peer Review*:

> *[I]n the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results. "Early" peer review occurs in time to focus attention on data inadequacies in time for corrections*.[23]

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[19] *Supra* note 5.

[20] *Supra* note 14 at 11.

[21] *See* "Final Information Quality Bulletin for Peer Review," Memorandum from Joshua B. Bolten, Director, Office of Management and Budget to Heads of Departments and Agencies, p. 15 (Dec. 16, 2004) (citing Mark R. Powell, *Science at EPA: Information in the Regulatory Process*, Resources for the Future, Washington, D.C., 1999: 139).

[22] *Supra* note 14 at 41.

[23] *Supra* note 21 at 14.

To this end, agencies should establish transparent protocols and standards for data identification, interpretation and characterization in conformity with the National Academy of Sciences recommendations. Such an approach includes:

- Establishing standard protocols for evidence identification;
- Developing a template for description of the search approach;
- Establishing protocols for review of major types of studies, such as epidemiologic and bioassay;
- Standardizing the approach to using weight-of-evidence guidelines;
- Conducting agency workshops on approaches to implementing weight-of-evidence guidelines;
- Expanding and harmonizing the approach for characterizing uncertainty and variability; and
- Establishing clear guidelines for study selection, which include balancing the strengths and weaknesses of studies, weighing human versus experimental evidence, and determining whether combining estimates among studies is warranted.[24]

When circulating draft and final hazard assessments for review, the agency staff should clearly describe the relevant positive and negative evidence, the limitations inherent in the data, and the uncertainties and divergent results presented. As emphasized in the White House's Memorandum on Scientific Integrity:

> *The accurate presentation of scientific and technological information is critical to informed decision-making by the public and policymakers. Agencies should communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections, including best-case and worst-case scenarios where appropriate.*[25]

Such transparency will not only ensure informed decision-making, but will also reduce the likelihood of legal challenges to the regulatory action and increase the probability that, in the event of a legal challenge, the regulatory action stemming from a scientific review is upheld by reviewing bodies, such as a court.

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[24] *See*, National Academy of Sciences "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," Ch. 7 (Apr. 2011), *available at* http://www.nap.edu/catalog/13142.html.

[25] *Supra* note 4 at 2.

C. Meaningful and Timely Scientific Dialogue Among the Agency, its Review Panels, and the Outside Scientific Community

The first step to strengthening how agencies communicate science is *communication*. Put simply, agencies must strengthen the dialogue between the staff, agency review panels, and the outside scientific community in order to draw upon the available expertise and diversity of scientific perspectives.[26] OMB's *Final Information Quality Bulletin for Peer Review* recognizes the value of obtaining diverse scientific input:

> *On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (e.g., the National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports.*[27]

We recognize that the focus of the ACUS study paper is internal agency communications. In many or most cases, however, the agency does not complete its internal communications before engaging in external communications. Particularly when review panels and the outside scientific community are engaged by the agency, the same principles of transparent communication and process should be observed. The need to engage all members of the scientific community, within and outside the agency, is especially critical in light of steadily diminishing government funding for research and increased expectations that industry bear the burden of proving the safety of their chemicals, products and practices.

The agency should also seek to gain outside scientific input because the most relevant, current data are typically developed and best-understood by outside stakeholders with the resources and interest to support such work. In conjunction with an appropriately broad charge, agencies must provide to the members of their review panels all relevant studies brought to light through public comment so that the reviewers can render a meaningful weight of evidence evaluation.[28] Mere access to such information in a public docket is simply not enough given the volume of information submitted and the time constraints of peer review. A good faith agency effort to ensure sound peer review would include providing reviewers with accurate and helpful summaries of critical public comments. Engagement with outside scientists should go beyond brief comment periods, and should include established practices of the scientific community, such as the holding of symposia.

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[26] *See supra* note 21 at 16-17 (stating that the two critical factors in selecting reviewers is expertise and balance).

[27] *Id*.

[28] *See* "OMB Proposes Draft Peer Review Standards for Regulatory Science," p. 4, Office of Management and Budget (Aug. 29, 2003).

Finally, it is critical that agencies provide *timely* responses to relevant comments from the public and their own review panels. Although this may serve external communications purposes at some point, the initial value is a support for careful internal review and critique of agency work product. Carefully reviewing and preparing written responses to comments before starting the next step in a policy-setting process helps to ensure that the agency has the benefit of data and analyses from a variety of sources early in the process, before the agency staff has committed to an unsubstantiated or malformed position. Further, the analysis of and responses to relevant outside comments, especially those that differ from the agency's position, are necessary for effective final work product.

D. Some Final Points

- Public trust in agency expertise and decision-making stems, in large part, from a perception of fair and reasoned decision-making. This is particularly true in the context of regulatory science, as the vast majority of the public lacks the solid grounding in basic sciences, scientific principles and the scientific method necessary to critically assess science in the administrative process. Accordingly, to strengthen the communication of science, agencies should develop a transparent framework setting forth how they will consistently approach and distinguish between scientific data, the interpretation and evaluation of data, and regulatory policy. While these concepts are necessarily inseparable in the context of regulatory science, their roles are unique and limited. Scientific data in isolation rarely answer the questions posed by Congress, the White House or regulatory agencies. To formulate an answer the data must be interpreted, and after the data are interpreted the agency must decide, *as a matter of policy*, how to reconcile scientific uncertainty, weigh risk, and determine appropriate administrative action. Protocols for approaching the stages involved in risk management decision-making would undoubtedly strengthen agency accountability and reliance on agency expertise.
- Agency documents should clarify that they are not presenting scientific fact, but rather a policy judgment informed by their scientific literature review and the applicable statutory or regulatory criteria.
- As a corollary, agencies must explicate - on the science side - the scope of their literature review, the limitations, uncertainties and divergent results of the data, their assumptions and their methods of analysis, and - on the policy side - the statutory or regulatory criteria, as well as the impact of the regulatory decision.
- Prior to beginning the review of scientific data, agencies should explain and seek substantive guidance on their approach to conducting a literature review and their methods for filtering and evaluating studies. Once the agency has committed to a position, early review of methodology will ultimately save resources by minimizing the likelihood of legal challenges that would otherwise arise near the end of an assessment.

- Review panels must be given enough time and a broad enough charge to review relevant stakeholder input and additional scientific data, to identify scientific uncertainties and to characterize the potential implications of those uncertainties on the technical conclusions drawn.
- If a risk profile does not clearly satisfy the legal criteria for regulatory action, then briefing memoranda and other correspondence directed to agency heads should scrupulously describe how the staff interpreted the scientific data and the default assumptions they employed.

IV. Conclusion

Good science and good administrative practices share common elements and should be mutually reinforcing. Internal agency communications would benefit by ensuring transparency and meaningful, timely dialogue among the agency, its review panels, and outside stakeholders. While these principles would benefit many types of administrative processes, they are essential in the field of "regulatory science," where the amoral discipline of science and the value-based exercise of policymaking come together. In this context, transparency includes clearly distinguishing the roles science, data interpretation, and regulatory policy play in administrative risk management decision-making.

We appreciate the opportunity to provide our comments on this important issue and would be happy to discuss or elaborate as the project progresses.

Respectfully submitted,

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